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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/510,329	11/11/2005	Franz-Christoph Bange	P/2107-259	7517

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EXAMINER

STAPLES, MARK

ART UNIT PAPER NUMBER

1637

DATE MAILED: 05/23/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/510,329

Applicant(s)

BANGE ET AL.

Examiner

Mark Staples

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Election/Restrictions

1. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Sequence restriction is also made for certain groups. See section 3.

Group I, claims 1-11 drawn to methods for detection of a mycobacterial infection by means of primer pair of SEQ ID NO: 1 and SEQ ID NO: 5, SEQ ID NO: 2 and primer pairs of SEQ ID NO: 3, or SEQ ID NO: 4 and SEQ ID NO: 5; by means of a genus-specific probe pair which includes the sequences of SEQ ID NO: 10 and SEQ ID NO: 11; by means of species-specific pairs of probes including the sequences of SEQ ID NO: 6 and SEQ ID No: 7 or SEQ ID NO: 8 and SEQ ID NO: 9 and the complementary sequences thereof; and by means of at least one artificial plasmid as an internal standard.

Group II, claim 12, drawn to an oligonucleotide primer pair comprising SEQ ID NO: 2 and SEQ ID NO: 3.

Group III, claim 13, drawn to an oligonucleotide primer comprising SEQ ID NO: 4.

Group IV, claim 14, drawn to an oligonucleotide hybridization probe pair comprising SEQ ID NO: 6 and SEQ ID NO: 7 and their complementary sequences.

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Group V, claim 15, drawn to an oligonucleotide hybridization probe pair comprising SEQ ID NO: 8 and SEQ ID NO: 9 and their complementary sequences.

Group VI, claim 16, drawn to an oligonucleotide hybridization probe pair comprising SEQ ID NO: 10 and SEQ ID NO: 11 and their complementary sequences.

Group VII, claims 17-20, drawn to an artificial plasmid which can be employed as an internal control of amplification for detection of mycobacteria including nucleotide sequences SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, or SEQ ID NO: 17.

Group VIII, claims 21 and 22, drawn to diagnostic kits for specific detection of a mycobacterial infection, including at least one primer pair comprising SEQ ID NO: 4, one hybridization probe pair comprising SEQ ID NO: 10 and SEQ ID NO: 11, one species-specific probe pair of SEQ ID NO: 6 and SEQ ID NO: 7 or SEQ ID NO: 8 and SEQ ID NO: 9; and comprising an artificial plasmid including the sequences of SEQ ID NO: 14, SEQ ID NO: 15, SEQ ID NO: 16, or SEQ ID NO: 17.

2. The inventions listed as Groups I through VIII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

The technical feature linking Groups I through VIII appears to be that they all relate to detection of mycobacteria.

However, Hance et al (1989) teach detection of mycobacteria.

Therefore the technical feature linking the inventions of Groups I through VIII does not constitute a special technical feature as defined by PCT Rule 13.2, as it does not define a contribution over the prior art.

Furthermore, each Group has a different special technical feature of either: (a) steps of extracting, amplifying, and detecting mycobacterial DNA using sequences including SEQ ID NOs 1-11, (b) primers comprising specific and distinct sequences per SEQ ID NOs 2-4, (c) probes comprising specific and distinct sequences per SEQ ID NOs 6-11, (d) artificial plasmids comprising specific and distinct sequences per SEQ ID NOs 14-17, or (e) diagnostic kits including a polymerase and DNA sequences comprising SEQ ID NOs 2-4, 10-11, and 14-17. Group I claims steps, Groups II and III each claim distinct primers, Groups IV-VI each claim distinct pairs of probes, Group VII claims distinct artificial plasmids, and Group VIII claims diagnostic kits including several components.

Accordingly, Groups I through VIII are not so linked by the same or corresponding special technical feature as to form a single general inventive concept.

Sequence Restriction

3. Each sequence within a Group comprises a patentably distinct subgroup. Groups with patently distinct subgroups are Groups I, VII, and VIII. Upon election of one of these Groups, Applicant is required to also elect a restriction subgroup. This is not a species election. Applicant will be required to cancel non-elected subject matter upon indication of allowable subject matter.

If applicant elects Group I, applicant is required to elect **one** pair of primers and **one** pair of species-specific probes to which the claims shall be restricted (MPEP § 803.04). It is noted that genus-specific hybridization probe pairs include only one pair of sequences and that no sequence is given for artificial plasmids of this group.

If applicant elects Group VII, applicant is required to elect **one** artificial plasmid for prosecution on the merits to which the claims shall be restricted (MPEP § 803.04).

If applicant elects Group VIII, applicant is required to elect **one** species-specific pair of probes and **one** artificial plasmid for prosecution on the merits to which the claims shall be restricted (MPEP § 803.04). It is noted that that genus-specific hybridization probe pairs include only one pair of sequences for this group.

4. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the

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record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Staples whose telephone number is (571) 272-9053. The examiner can normally be reached on Monday through Friday, 9:00 a.m. to 6:00 p.m.

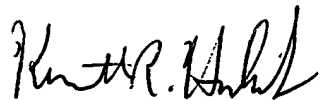
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Staples
Examiner
Art Unit 1637
May 17, 2006



KENNETH R. HORLICK, PH.D
PRIMARY EXAMINER
5/17/06